WHAT IS CLAIMED AS BEING NOVEL & UNOBVIOUS IN UNITED STATES LETTERS PATENT IS:

108. An aerosolizable or sprayable composition, comprising a carrier, a nucleic acid(s) that comprise(s) one or more oligonuceleotide(s) (oligo(s)) effective to alleviate hyper-responsiveness to, and/or increased levels of, adenosine, and/or bronchoconstriction, and/or asthma, and/or lung allergy(ies) and/or lung inflammation, and/or to reduce levels of adenosine receptor(s), the oligo being anti-sense to an initiation codon, a coding region or a 5' or 3' intron-exon junction of a gene(s) encoding an adenosine A_1, A_{2a}, A_{2b} or A_3 receptor(s) or being anti-sense to their corresponding mRNA(s), pharmaceutically and veterinarily acceptable salts of the oligo(s) or mixtures thereof, and a surfactant that may be operatively linked to the nucleic acid; wherein when the adenosine receptor(s) comprise(s) an adenosine A_{2a} and/or A_{2b} receptor(s), the composition need not comprise a surfactant(s).

109. The composition of claim 108, wherein the oligo consists of up to about 10% A.

110. The composition of claim 109, wherein the oligo consists of up to about 5% A.

111. The composition of claim 110, wherein the oligo consists of up to about 3% A.

112. The composition of claim 111, wherein the oligo is A-free.

113. The composition of claim 108, wherein the oligo is anti-sense to the initiation codon of the mRNA, to the 5' or 3' intron-exon junctions or to sequences of the coding region comprising 2 or more G and/or C of the adenosine A_1 receptor gene.

114. The composition of claim 108, wherein the oligo is anti-sense to the initiation codon of the mRNA, to the 5' or 3' intron-exon junctions or to sequences of the coding region comprising 2 or more G and/or C of the adenosine A_{2a}, A_{2b} and/or A_3 receptors.

115. The composition of claim 108, wherein if the oligo contains adenosine (A), at least one A is substituted by a universal base selected from heteroaromatic bases that bind to a thymidine base but have antagonist activity or less than about 0.3 of the adenosine base agonist activity at the adenosine A_1, A_{2b} or A_3 receptors, or heteroaromatic bases that have no activity or have agonist activity at the adenosine A_{2a} receptor.

116. The composition of claim 115, wherein substantially all As are substituted by a universal base (s) selected from heteroaromatic bases that bind to a thymidine base but either have antagonist activity or less than about 0.3 of the adenosine base agonist activity at the adenosine A_1, A_{2b} or A_3 receptors, or heteroaromatic bases that have no activity or have agonist activity at the adenosine A_{2a} receptor.

117. The composition of claim 115, wherein the heteroaromatic bases are selected from pyrimidines or purines that may be substituted by O, halo, NH_2, SH, SO, SO_2, SO_3, COOH, or branched or fused primary or secondary amino, alkyl, alkenyl, alkynyl, cycloalkyl, heterocycloalkyl, aryl,

heteroaryl, alkoxy, alkenoxy, acyl, cycloacyl, arylacyl, alkynoxy, cycloalkoxy, aroyl, arylthio, arylsulfoxyl, halocycloalkyl, alkylcycloalkyl, alkenylcycloalkyl, alkynylcycloalkyl, haloaryl, alkylaryl, alkenylaryl, alkynylaryl, arylalkyl, arylalkenyl, arylalkynyl, or arylcycloalkl, which may be further substituted by O, halo, NH_2, primary, secondary or tertiary amine, SH, SO, SO_2, SO_3, cycloalkyl, heterocycloalkyl or heteroaryl.

118. The composition of claim 117, wherein the pyrimidines are substituted at a 1, 2, 3, and/or 4 position, and the purines are substituted at a 1, 2, 3, 4, 7 and/or 8 position.

119. The composition of claim 118, wherein the pyrimidines or purines are selected from theophylline, caffeine, dyphylline, etophylline, acephylline piperazine, bamifylline, enprofylline or xanthine.

120. The composition of claim 116, wherein the universal base is selected from 3 – nitropyrrole-2'-deoxynucleoside, 5-nitroindole, 2-deoxyribosyl-(5-nitroindole), 2- deoxyribofuranosyl – (5 – nitroindole), 2' – deoxyinosine, 2' – deoxynebularine, 6H, 8H – 3, 4 – dihydropyrimido [4, 5 – c] oxazine – 7 – one or 2 – amino – 6 – methoxyaminopurine.

121. The composition of claim 108, wherein a methylated cytosine (^{m}C) is substituted for an unmethylated cytosine (C) in at least one CpG dinucleotide if present in the nucleic acid(s).

122. The composition of claim 108, wherein at least one monoculeotide is linked or modified by one or more of phosphorothioate, phosphorodithioate, phosphorotrithioate, methylphosphonate, phosphoramidate, boranophosphate, phosphotriester, formacetal, 2'-O- methyl, thioformacetal, 5'-thioether, carbonate, 5'-N-carbamate, sulfate, sulfonate, sulfamate, sulfonamide, sulfone, sulfite, sulfoxide, sulfide, hydroxylamine, methylene (methylimino) (MMI) and methyleneoxy (methylimino) (MOMI), terminal 1,3-propanediol, terminal dodecanol, 2'-O- methoxyethyl, C-5-propynyl pyrimidine, C-5 methyl cytidine, C-5 ethynyl pyrimidine, 2' propoxy, C-18 amine, N3'-P5 phosphoramidates, 3'-alkylamino, 2'-fluoro; 5-fluoro pyrimidine, 5- iodo pyrimidine, 5-bromo pyrimidine, 2'-borano, C-5 hexynyl pyrimidine, 2'-O-(2-methoxy)ethyl, 2'-O-aminopropyl, 5-(phenylethyl) or peptide nucleic acid interbase linkages or conjugated to a polyethylene glycol, cholesterol, cholesteryl, dehydroepiandrosterone sulfatide (DHEA), dehydroepiandrosterone sulfate (DHEASulfate), dehydroepiandrosterone sulfatide (DHEASulfatide), ubiquinone (CoQn), dolichol, poly L-lysine, sulfatidic acid or fatty acids.

123. The composition of claim 122, wherein substantially all mononucleotides are linked or modified by one or more of phosphorothioate, phosphorodithioate, phosphorotrithioate, methylphosphonate, phosphoramidate, boranophosphate, phosphotriester, formacetal, 2'-O- methyl, thioformacetal, 5'-thioether, carbonate, 5'-N-carbamate, sulfate, sulfonate, sulfamate, sulfonamide, sulfone, sulfite, sulfoxide, sulfide, hydroxylamine, methylene (methylimino) (MMI) and methyleneoxy

(methylimino) (MOMI), terminal 1,3-propanediol, terminal dodecanol, 2'-O- methoxyethyl, C-5-propynyl pyrimidine, C-5 methyl cytidine, C-5 ethynyl pyrimidine, 2'-propoxy, C-18 amine, N3'-P5' phosphoramidates, 3'-alkylamino, 2'-fluoro; 5-fluoro pyrimidine, 5-iodo pyrimidine, 5-bromo pyrimidine, 2'-borano, C-5 hexynyl pyrimidine, 2'-O-aminopropyl, 5-(phenylethyl) or peptide nucleic acid interbase linkages or conjugatd to a polyethylene, glycol, cholestrol, cholesteryl, dehydroepiandrosterone (DHEA), dehydroepiandrosterone sulfate (DHEASulfate), dehydroepiandrosterone sulfatide (DHEASulfatide), ubiquinone (CoQn), dolichol, poly L-lysine, sulfatidic acid or fatty acids.

124. The composition of claim 108, wherein the anti-sense oligo comprises 7 to 60 mononucleotides.

125. The composition of claim 108, wherein the oligo comprises a sequence selected from SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5 or DEQ ID NO: 7 to SEQ ID NO: 998, or SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5 or SEQ ID NO: 7 to SEQ ID NO: 998, wherein at least one mononucleotide is linked or modified by one or more of phoshporothioate, phosphorodithioate, phosphorotriester, formacetal, 2'-O-methyl, thioformacetal, 5'-thioether, carbonate, 5'-N-carbamate, sulfate, sulfonate, sulfamate, sulfonamide, sulfone, sulfite, sulfoxide, sulfide, hydroxylamine, methylene (methylimino) (MMI) and methyleneoxy (methylimino) (MOMI), terminal 1,3-propanediol, terminal dodecanol, 2'-O-methoxyethyl, C-5-propynyl pyrimidine, C-5 methyl cytidine, C-5 ethynyl pyrimidine, 2'-propoxy, C-18 amine, N3'-P5' phosphoramidates, 3'-alkylamino, 2'-fluoro; 5-fluoro pyrimidine, 5-iodo pyrimidine, 5-bromo pyrimidine, 2'-borano, C-5 hexynyl pyrimidine, 2'-O-(2-methoxy)ethyl, 2'-O-aminopropyl, 5-(phenylethyl) or peptide nucleic acid interbase linkages or conjugated to a polyethylene glycol, cholesterol, cholesteryl, dehydroepiandrosterone (DHEA), dehydroepiandrosterone sulfate (DHEA Sulfate), dehydroepiandrosterone sulfatide (DHEA Sulfatide), ubiquinone (CoQn), dolichol, poly L-lysine, sulfatidic acid or fatty acids.

126. The composition of claim 108, wherein the nucleic acid is linked to an agent that enhances cell internalization or up-take and/or a cell targeting agent.

127. The composition of claim 126, wherein the cell internalization or up take enhancing agent is a transferrin, asialoglycoprotein or a streptavidin.

128. The composition of claim 126, wherein the cell targeting agent comprises a vector, and the nucleic acid is operatively linked to the vector.

129. The composition of claim 128, wherein the vector comprises a prokaryotic or eukaryotic vector.

130. The composition of claim 108, wherein the surfactant comprises surfactant proteins, phospholipids, fatty acids, or surfactant-associated proteins.

131. The composition of claim 130, wherein the surfactant comprises polyoxy ethylene 23 lauryl ether (Brij 35®), t-octyl phenoxy polyethoxy ethanol (Triton X-100®), dipalmitoyl phosphatidyl choline (DPPC) and phosphatidyl glycerol (PG) (ALEC®), tyloxapol (Exosurf®), phospholipids, fatty acids, surfactant-associated proteins (Survanta®) or $C_{22}H_{19}C_{10}$ (Atovaquone®).

132. The composition of claim 108, wherein the carrier comprises a biologically acceptable carrier.

134. The composition of claim 108, wherein the carrier is a pharmaceutically or veterinarily acceptable carrier.

135. The composition of claim 134, wherein the carrier is selected from liquid or solid carriers.

136. The composition of claim 108, further comprising an agent selected from therapeutic agents other than the nucleic acid(s), antioxidants, flavoring or coloring agents, fillers, volatile oils, buffering agents, dispersants, RNA inactivating agents, flavoring agents, propellants or preservatives.

137. The composition of claim 136, comprising a pharmaceutically or veterinarily acceptable carrier, the nucleic acid, a surfactant, and other therapeutic agents.

138. The composition of claim 136, wherein the RNA inactivating agent comprises an enzyme.

139. The composition of claim 138, wherein the enzyme comprises a ribozyme.

140. The composition of claim 108, further comprising a propellant.

141. The composition of claim 108, wherein the nucleic acid is present in an amount of about 0.01 to about 99.99 w/w of the composition.

143. The formulation of claim 108, selected from intrabuccal, intrapulmonary, respirable, nasal, inhalable, intracavitary, intraorgan, or slow release formulations.

144. The formulation of claim 143, wherein the carrier is selected from a solid or liquid carrier.

146. The formulation of claim 108, which comprises a sprayable or aerosolizable powder, solution, suspension or emulsion.

148. The formulation of claim 108, which comprises a sprayable or aerosolizable aqueous or alcoholic solution or suspension, oily solution or suspension, or oil-in-water or water-in-oil emulsion.

151. A capsule or cartridge, comprising the formulation of claim 143.

152. The sprayable or aerosolizable formulation of claim 146, comprising a sprayable or aerosolizable solid powder.

153. The formulation of claim 108, wherein the carrier comprises a hydrophobic carrier.

158. The formulation of claim 143, which comprises an intrapulmonary, intracavitary or intraorgan liquid or solid powdered formulation of particle size about 0.5μ to 10 μ, or 10 μ to 500 μ.

159. The formulation of claim 143, which comprises a nasal formulation of particle size 10 μ to 500 μ.

161. The formulation of claim 143, in bulk, or in single or multiple unit dose form.

162. The formulation of claim 143, which is a respirable or inhalable formulation comprising a solid powdered or liquid aerosol or spray of particle size about 0.5 μ to 10 μ.

163. A single cell, comprising the nucleic acid of claim 108.

164. A diagnostic or therapeutic kit for delivery of an oligonucleotide(s) (oligo(s)) comprising, in separate containers,

the delivery device of claim 222;

a nucleic acid comprising at least one oligonucleotide (oligo), their mixtures or their pharmaceutically or veterinarily acceptable salts; and

instructions for preparation of a non-liposomal respirable, inhalable, nasal, intrapulmonary, intraorgan, or intracavitary formulations of the nucleic acid of particle size about 0.5 to 500 μ and for its use; and

optionally an agent selected from therapeutic or diagnostic agents other than the oligo(s), anti-oxidants, fillers, volatile oils, dispersants, anti-oxidants, flavoring agents, propellants, preservatives, solvents, surfactants, buffering agents, RNA inactivating agents, agents that are internalized or up-taken by a cell, or coloring agents.

165. The kit of claim 164, wherein the delivery device delivers single metered doses of a solid powdered or liquid aerosol or spray inhalable, respirable, intracavitary, intraorgan or intrapulmonary formulation of the nucleic acid of particle size about 0.5 μ to 10 μ.

166. The kit of claim 164, wherein the device is adapted for receiving and piercing or opening a capsule(s) or cartridge(s) and producing a solid powdered or liquid aerosol or spray; and the nucleic acid is provided separately in a piercable or openable capsule(s) or cartridge(s) as a non-liposomal nasal, inhalable, respirable, intrapulmonary, intracavitary or intraorgan formulation of the nucleic acid.

167. The kit of claim 164, wherein the delivery device comprises a pressurized device that delivers a solid powdered or liquid aerosol or spray of particle size about 0.5 μ to 10 μ; and the nucleic acid is provided as a non-liposomal suspension, solution, emulsion or dry powdered aerosolizable or sprayable formulation of about 0.5 μ to 10 μ.

168. The kit of claim 164, comprising the delivery device, a surfactant, the nucleic acid and other therapeutic agents.

169. The kit of claim 164, wherein the solvent is selected from organic solvents or organic solvents mixed with one or more co-solvents.

170. The kit of claim 164, wherein the device is adapted for receiving a capsule(s) or cartridge(s), and the nucleic acid is separately provided as a non-liposomal inhalable, respirable, nasal, intracavitary, intraorgan or intrapulmonary formulation in a capsule(s) or cartridge(s).

171. The kit of claim 164 further comprising, in separate containers, a propellant, pressurized means for delivery adapted for delivering a solid powdered or liquid aerosol or spray, and instructions for loading into the delivery device the nucleic acid as an inhalable, respirable, nasal, intracavitary, intraorgan or intrapulmonary formulation of particle size about 0.5μ to 500 μ, and then joining the device with the propellant and the pressurized means.

172. The kit of claim 167, wherein the pressurized inhaler further comprises a propellant and means for delivery of the propellant, and delivers the nucleic acid as a liquid or solid powdered aerosol or spray formulation.

173. An in vivo method of delivering a pharmaceutical composition to a target polynucleotide(s), comprising administering to the airways of a subject an aerosol or spray non-liposomal composition of particle size about 0.5 μ to 500 μ comprising a nucleic acid(s) that comprises at least one oligonucleotide(s) (oligo(s)).

178. The method of claim 173, wherein the composition is administered intrapulmonary, intraorgan, intracavitarily, intrabuccally, intranasally, by inhalation or into the subject's respiratory system.

179. The method of claim 173, wherein the oligo(s) is(are) anti-sense to the initiation codon, the coding region or the 5' or 3' intron-exon junctions of a gene encoding a protein associated with hyper-responsiveness to, and/or increased levels of, adenosine and/or levels of adenosine receptor(s), bronchoconsriction, asthma and/or lung allergy(ies), and/or lung inflammation, or being anti-sense to the corresponding mRNA, and is(are) effective to reduce hyper-responsiveness to adenosine, and/or the amount of adenosine receptor(s) and/or the production or availability of adenosine, and/or to increase the degradation of the adenosine receptor(s) and/or its(their) mRNA(s).

180. The method of claim 178, wherein the oligo(s) is(are) administered directly into the subject;s lung(s), intraorgan, intracavitarily, intrabuccal or intrapulmonarily.

181. The method of claim 173, wherein the composition comprises solid powdered or liquid particles of the nucleic acid(s) about 0.5 to 10 μ in size.

183. The method of claim 173, wherein the composition is administered as powdered solid or liquid nucleic acid particles 10 μ to 500 μ in size.

184. The method of claim 173, further comprising administering a surfactant, which may be in the same composition as the nucleic acid.

185. The method of claim 179, wherein the hyper-responsiveness to and/or increased levels of, adenosine and/orlevels of adenosine (A) receptor(s), and/or asthma and/or lung allergy(ies) and/or lung inflammation is associated with bronchoconstriction, of lung airways.

186. The method of claim 185, wherein the hyper-responsiveness to, or increased levels of, adenosine, levels of adenosine (A) receptor(s), and/or bronchoconstriction, and/or lung allergy(ies) and/or lung inflammation is(are) associated with COPD, asthma, ARDS, RDS,CF or side effects of adenosine administration.

187. The method of claim 179, wherein the hyper-responsiveness to, or increased levels of, adenosine, levels of adenosine (A) receptor(s), and/or bronchoconstriction, and/or asthma, and/or lung allergy(ies) and/or lung inflammation is(are) associated with inflammation or an inflammatory disease.

188. The method of claim 173, wherein the composition further comprises other therapeutic agents.

189. The method of claim 188, wherein the therapeutic agent(s) comprise(s) anti-adenosine A_1, A_{2b} or A_3 receptor agents or adenosine A_{2a} receptor stimulating agents other than the nucleic acid(s).

190. The method of claim 184, wherein the surfactant comprises a surfactant protein, non-liposomal phospholipid, fatty acid, or surfactant-associated protein .

192. The method of claim 173, wherein the subject is a mammal.

193. The method of claim 192, wherein the mammal is a human or a non-human mammal.

195. The method of claim 173, wherein the nucleic acid is administered in an amount of about 0.005 to about 150 mg/kg body weight.

196. The method of claim 195, wherein the nucleic acid is administered in an amount of about 0.01 to about 75 mg/kg body weight.

197. The method of claim 196, wherein the nucleic acid is administered in an amount of about 1 to about 50 mg/kg body weight.

198. The method of claim 173, which is a prophylactic or therapeutic method.

200. The method of claim 179, wherein the nucleic acid is obtained by

(a) selecting fragments of a target nucleic acid having at least 4 contiguous bases consisting of G or C; and

(b) obtaining a second oligo 4 to 60 nucleotides long comprising a sequence that is anti-sense to the selected fragment.

201. The method of claim 173, wherein the oligo consists of up to about 10% A.

202. The method of claim 201, wherein the oligo consists of up to about 5% A.

203. The method of claim 201, wherein the oligo consists of up to about 3% A.

204. The method of claim 203, wherein the oligo is A-free.

205. The method of claim 179, wherein the oligo is anti-sense to the initiation codon, the coding region or the 5' or 3' intron-exon junctions of a gene encoding an adenosine A_1, A_{2b} or A_3 receptor, and the composition may further comprise a surfactant.

206. The method of claim 173, wherein if the oligo contains A, at least one A is substituted with a universal base selected from heteroaromatic bases which bind to a thymidine base but have antagonist activity or less than about 0.3 of the adenosine base agonist activity at the adenosine A_1, A_{2b} or A_3 receptors, or heteroaromatic bases which have no activity or have agonist activity at the adenosine A_{2a} receptor.

207. The method of claim 206, wherein substantially all As are substituted with universal bases selected from heteroaromatic bases which bind to a thymidine base but have antagonist activity or less than about 0.3 of the adenosine base agonist activity at the adenosine A_1, A_{2b} or A_3 receptors, or heteroaromatic bases which have no activity or have agonist activity at the adenosine A_{2a} receptor.

208. The method of claim 206, wherein the heteroaromatic bases are selected from pyrimidines or purines that may be substituted by O, halo, NH_2, SH, SO, SO_2, SO_3, COOH, branched fused primary secondary amino, alkyl, alkenyl, alkynyl, cycloalkyl, heterocycloalkyl, aryl, heteroaryl, alkoxy, alkenoxy, acyl, cycloacyl, arylacyl, alkynoxy, cycloalkoxy, aroyl, arylthio, arylsulfoxyl, halocycloalkyl, alkylcycloalkyl, alkenylcycloalkyl, alkynylcycloalkyl, haloaryl, alkylaryl, alkenylaryl, alkynylaryl, arylalkyl, arylalkenyl, arylalkynyl, arylcycloalkl, all of which may be further substituted by O, halo, NH_2, primary, secondary and tertiary amine, SH, SO, SO_2, SO_3, cycloalkyl, heterocycloalkyl or heteroaryl.

209. The method of claim 208, wherein the pyrimidines are substituted at positions 1, 2, 3 and/or 4, and the purines are substituted at positions 1, 2, 3, 4, 7 and/or 8.

210. The method of claim 209, wherein the pyrimidines and purines are selected from theophylline, caffeine, dyphylline, etophylline, acephylline piperazine, bamifylline, enprofylline or xanthine.

211. The method of claim 206, wherein the universal base comprises 3-nitropyrrole-2'-deoxynucleoside, 5-nitro-indole, 2-deoxyribosyl-(5-nitroindole), 2-deoxyribofuranosyl-(5-nitroindole), 2'-deoxyinosine, 2'-deoxynebularine, 6H, 8H-3,4-dihydropyrimido [4,5-c] oxazine-7-one or 2-amino-6-methodxyaminopurine.

212. The method of claim 173, further comprising methylating at least one cytosine vicinal to a guanosine into a methylated cytosine (^{m}C) if a CpG dinucleotide is present in the oligo(s).

213. The method of claim 173, further comprising modifying or substituting at least one mononucleotide of the anti-sense oligo(s) with methylphosphonate, phosphotriester, phosphorothioate, phosphorodithioate, boranophosphate, formacetal, thioformacetal, thioether, carbonate, carbamate, sulfate, sulfonate, sulfamate, sulfonamide, sulfone, sulfite, sulfoxide, sulfide, hydroxylamine, methylene(methyimino), methyleneoxy (methylimino), 2'-O-methyl, phosphoramidate residues, or combinations thereof.

214. The method of claim 213, wherein substantially all mononucleotides are substituted and/or modified.

215. The method of claim 173, further comprising operatively linking the nucleic acid to an agent that enhances cell internalization or up-take, or a cell targeting agent.

216. The method of claim 215, wherein the cell internalization or up-take enhancing agent is selected from transferrin, asialoglycoprotein or streptavidin.

217. The method of claim 215, wherein the cell targeting agent comprises a vector.

218. The method of claim 217, wherein the vector to which the agent is operatively linked comprises a prokaryotic or eukaryotic vector.

219. The method of claim 179, wherein the nucleic acid comprises an oligo of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5 or SEQ ID NO: 7 to SEQ ID NO: 998, or SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5 or SEQ ID NO: 7 to SEQ ID NO: 998, wherein at least one mononucleotide is linked or modified by one or more of phosphorothioate, phosphorodithioate, methylphosphonate, phosphoramidate, boranophosphate, phosphotriester, formacetal, 2'-O- methyl, thioformacetal, 5'-thioether, carbonate, 5'-N-carbamate, sulfate, sulfonate, sulfamate, sulfonamide, sulfone, sulfite, sulfoxide, sulfide, hydroxylamine, methylene (methylimino) (MMI) and methyleneoxy (methylimino) (MOMI), terminal 1,3-propanediol, terminal dodecanol, 2'-O- methoxyethyl, C-5-propynyl pyrimidine, C-5 methyl cytidine, C-5 ethynyl pyrimidine, 2' propoxy, C-18 amine, N3'-P5 phosphoramidates, 3'-alkylamino, 2'-fluoro; 5-fluoro pyrimidine, 5- iodo pyrimidine, 5-bromo pyrimidine, 2'-borano, C-5 hexynyl pyrimidine, 2'-O-(2-methoxy)ethyl, 2'-O-aminopropyl, 5-(phenylethyl) or peptide nucleic acid interbase linkages or conjugated to a polyethylene glycol, cholesterol, cholesteryl, dehydroepiandrosterone sulfatide (DHEA), dehydroepiandrosterone sulfate (DHEASulfate),

dehydroepiandrosterone sulfatide (DHEASulfatide), ubiquinone (CoQn), dolichol, poly L-lysine, sulfatidic acid or fatty acids.

220. The method of claim 191, wherein the surfactant comprises polyoxy ethylene 23 lauryl ether (Brij 35®), t-octyl phenoxy polyethoxy ethanol (Triton X-100®), dipalmitoyl phosphatidyl choline (DPPC) and phosphatidyl glycerol (PG) (ALEC®), tyloxapol (Exosurf®), phospholipids, fatty acids, surfactant-associated proteins (Survanta®) or $C_{22}H_{19}C_{10}$ (Atovaquone®).

221. The method of claim 179, wherein the hyper-responsiveness to, or increased levels of, adenosine, and/or increased levels of adenosine(A) receptor(s), and/or bronchoconstriction, and/or lung allergy(ies) and/or lung inflammation, is(are) associated with asthma or a disease or condition associated with asthma.

222. A diagnostic or therapeutic device adapted for delivering a non-liposomal respirable, inhalable, nasal, intrapulmonary, intraorgan, or intracavitary formulation of particle size about 0.5 μ to about 500 μ, the formulation comprising a nucleic acid(s) that comprise(s) at least one oligonucleotide (oligo(s)), their mixtures, or their pharmaceutically or veterinarily acceptable salts.

223. The device of claim 222, which is adapted for delivering single metered doses of the formulation as a solid powdered or liquid aerosol or spray of the nucleic acid of particle size about 0.5 μ to 10 μ.

224. The device of claim 222, which is adapted for receiving and piercing or opening a capsule(s) or cartridge(s), and for producing a solid powdered or liquid aerosol or spray of particle size about 0.5 μ to 500 μ and wherein the formulation is provided separately in a piercable or openable capsule(s) or cartridge(s) as a nasal, inhalable, respirable, intrapulmonary, intracavitary or intraorgan formulation of particle size about 0.5 μ to 500μ.

225. The device of claim 222, which comprises a pressurized device that delivers a solid powdered or liquid aerosol or spray formulation of particle size about 0.5 μ to 500 μ; wherein the formulation comprises a suspension, solution, emulsion or dry powder aerosol or spray of the nucleic acid.

226. The pressurized device of claim 225 further comprising, in separate containers, a propellant and pressurized means for delivery adapted for delivering a solid powdered or liquid aerosol or spray, and instructions for loading into the delivery device the inhalable, respirable, nasal, intracavitary, intraorgan or intrapulmonary formulation, and joining the device with the propellant and the pressurized delivery means.

227. The pressurized device of claim 225, further comprising a propellant and propellant delivery means, wherein the pressurized inhaler delivers the formulation as a liquid or solid powdered aerosol or spray.

228. The device of claim 222, which is adapted for receiving and piercing or opening a capsule(s) or cartridge(s), and wherein the formulation is provided separately in a capsule(s) or cartridge(s).

229. The kit of claim 164, wherein the oligo(s) is(are) anti-sense to the initiation codon, the coding region or the 5' or 3' region of a gene encoding a polypeptide selected from an adenosine A_1 receptor, adenosine A_{2a} receptor, adenosine A_{2b} receptor, or adenosine A_3 receptor.

230. The kit of claim 229, for diagnosis or treatment of sepsis, pulmonary vasoconstriction, lung inflammation, or lung allergies, asthma, impeded respiration, respiratory distress syndrome (RDS), acute respiratory distress syndrome (ARDS), pain, cystic fibrosis (CF), pulmonary hypertension, pulmonary vasoconstriction, emphysema or chronic obstructive pulmonary disease (COPD).

231. The kit of claim 164, wherein the nucleic acid comprises an oligo of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5 or SEQ ID NO: 7 to SEQ ID NO: 998, or SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5 or SEQ ID NO: 7 to SEQ ID NO: 998, wherein at least one mononucleotide is linked or modified by one or more of phosphorothioate, phosphorodithioate, methylphosphonate, phosphoramidate, boranophosphate, phosphotriester, formacetal, 2'-O- methyl, thioformacetal, 5'-thioether, carbonate, 5'-N-carbamate, sulfate, sulfonate, sulfamate, sulfonamide, sulfone, sulfite, sulfoxide, sulfide, hydroxylamine, methylene (methylimino) (MMI) and methyleneoxy (methylimino) (MOMI), terminal 1,3-propanediol, terminal dodecanol, 2'-O- methoxyethyl, C-5-propynyl pyrimidine, C-5 methyl cytidine, C-5 ethynyl pyrimidine, 2' propoxy, C-18 amine, N3'-P5 phosphoramidates, 3'-alkylamino, 2'-fluoro; 5-fluoro pyrimidine, 5- iodo pyrimidine, 5-bromo pyrimidine, 2'- borano, C-5 hexynyl pyrimidine, 2'-O-(2-methoxy)ethyl, 2'-O-aminopropyl, 5-(phenylethyl) or peptide nucleic acid interbase linkages or conjugated to a polyethylene glycol, cholesterol, cholesteryl, dehydroepiandrosterone sulfatide (DHEA), dehydroepiandrosterone sulfate (DHEASulfate), dehydroepiandrosterone sulfatide (DHEASulfatide), ubiquinone (CoQn), dolichol, poly L-lysine, sulfatidic acid or fatty acids.

232. The composition of claim 108, which comprises particle sizes of about 0.5 μ to 500 μ.

233. The nucleic acid of claim 108, which is operatively linked to a vector.

234. A single cell, comprising the nucleic acid(s) of claim 233.

Please add the following claims:

-- 235. The composition of claim 108, wherein the oligo(s) consist(s) of up to about 15% A.

236. The composition of claim 130, wherein the surfactant comprises surfactant protein A, surfactant protein B, surfactant protein C, surfactant protein D, surfactant protein E or active

fragments thereof, non-dipalmitoyl disaturated phosphatidylcholine, dipalmitoylphosphatidylcholine, phosphatidylcholine, phosphatidylglycerol, phosphatidylinositol, phosphatidylethanolamine, phosphatidylserine, phosphatidic acid, ubiquinones, lysophosphatidylethanolamine, lysophosphatidylcholine, palmitoyl-lysophosphatidylcholin, dehydroepiandrosterone, dolichols, sulfatidic acid, glycerol-3-phosphate, dihydroxyacetone phosphate, glycerol, glycerol-3-phosphocholine, dihydroxyacetone, palmitate, cytidine diphosphate (CDP) diacylglycerol, CDP choline, choline, choline phosphate, lamellar bodies, omega-3 fatty acids, polyenic acid, polyenoic acid, lecithin, palmitic acid, non-ionic ethylene and/or propylene oxide block copolymers, polyoxypropylene, polyoxyethylene, poly (vinyl amine) with dextran and/or alkanoyl side chains, polyoxy ethylene ethers, phenoxy polyethoxy alcohols, phosphatidyl choline esters, phosphatidyl ethers, tyloxapol, or $C_{22}H_{19}C_{10}$.

237. The kit of claim 164, wherein the surfactant comprises surfactant protein A, surfactant protein B, surfactant protein C, surfactant protein D, surfactant protein E or active fragments thereof, non-dipalmitoyl disaturated phosphatidylcholine, dipalmitoylphosphatidylcholine, phosphatidylcholine, phosphatidylglycerol, phosphatidylinositol, phosphatidylethanolamine, phosphatidylserine, phosphatidic acid, ubiquinones, lysophosphatidylethanolamine, lysophosphatidylcholine, palmitoyl-lysophosphatidylcholin, dehydroepiandrosterone, dolichols, sulfatidic acid, glycerol-3-phosphate, dihydroxyacetone phosphate, glycerol, glycerol-3-phosphocholine, dihydroxyacetone, palmitate, cytidine diphosphate (CDP) diacylglycerol, CDP choline, choline, choline phosphate, lamellar bodies, omega-3 fatty acids, polyenic acid, polyenoic acid, lecithin, palmitic acid, non-ionic ethylene and/or propylene oxide block copolymers, polyoxypropylene, polyoxyethylene, poly (vinyl amine) with dextran and/or alkanoyl side chains, polyoxy ethylene ethers, phenoxy polyethoxy alcohols, phosphatidyl choline esters, phosphatidyl ethers, tyloxapol, or $C_{22}H_{19}C_{10}$.

238. The kit of claim 164, wherein the delivery device delivers single metered doses of a solid powdered or liquid aerosol or spray buccal, nasal, intracavitary, intraorgan or intrapulmonary formulation of the nucleic acid of particle size 10 μ to 500μ.

239. The kit of claim 164, wherein the delivery device is adapted for receiving and piercing or opening a capsule(s) or cartridge(s) and producing a solid powdered or liquid aerosol or spray; and the nucleic acid is provided separately in a piercable or openable capsule(s) or cartridge(s) as an inhalable, respirable, intrapulmonary, intracavitary or intraorgan formulation of the nucleic acid(s) of particle size about 0.5 μ to 10 μ.

240. The kit of claim 164, wherein the delivery device is adapted for receiving and piercing or opening a capsule(s) or cartridge(s) and producing a solid powdered or liquid aerosol or spray, and the nucleic acid is provided separately in a piercable or openable capsule(s) or cartridge(s) as a

buccal, nasal, intracavitary, intraorgan, or intrapulmonary formulation of particle size 10 μ to 500 μ of the nucleic acid.

241. The kit of claim 164, wherein the delivery device comprises a pressurized device that delivers a solid powdered or liquid aerosol or spray of particle size 10 μ to 500 μ; and the nucleic acid is provided as an aerosolizable or sprayable suspension, solution, emulsion or dry powder formulation of particle size 10 μ to 500 μ.

242. The kit of claim 164, wherein the nucleic acid is provided as a buccal, nasal, intracavitary, intraorgan, or intrapulmonary formulation of particle size 10μ to 500μ.

243. The kit of claim 171, wherein the nucleic acid is provided as an inhalable, respirable, intracavitary, intraorgan or intrapulmonary formulation of particle size about 0.5μ to 10μ.

244. The device of claim 222, being adapted for delivering a solid powdered or liquid aerosol or spray formulation of the nucleic acid of particle size 0.5μ to 10μ.

245. The device of claim 222, being adapted for delivering a solid powdered or liquid aerosol or spray formulation of the nucleic acid of particle size 10μ to 500μ.

246. The device of claim 222, being adapted for delivering single metered doses of the formulation as a solid powdered or liquid aerosol or spray of the nucleic acid of particle size 10μ to 500μ.

247. The device of claim 222, wherein the oligo(s) is(are) anti-sense to the initiation codon, the coding region or the 5' or 3' intron-exon junctions of a gene encoding a protein associated with hyper-responsiveness to, and/or increased levels of, adenosine and/or levels of adenosine receptor(s), bronchoconsriction, asthma and/or lung allergy(ies), and/or lung inflammation, or being anti-sense to the corresponding mRNA, and is(are) effective to reduce hyper-responsiveness to adenosine, and/or the amount of adenosine receptor(s) and/or the production or availability of adenosine, and/or to increase the degradation of the adenosine receptor(s) and/or its(their) mRNA(s).

248. The method of claim 190, wherein the surfactant comprises surfactant protein A, surfactant protein B, surfactant protein C, surfactant protein D, surfactant protein E or active fragments thereof, non-dipalmitoyl disaturated phosphatidylcholine, dipalmitoylphosphatidylcholine, phosphatidylcholine, phosphatidylglycerol, phosphatidylinositol, phosphatidylethanolamine, phosphatidylserine, phosphatidic acid, ubiquinones, lysophosphatidylethanolamine, lysophosphatidylcholine, palmitoyl-lysophosphatidylcholin, dehydroepiandrosterone, dolichols, sulfatidic acid, glycerol-3-phosphate, dihydroxyacetone phosphate, glycerol, glycerol-3-phosphocholine, dihydroxyacetone, palmitate, cytidine diphosphate (CDP) diacylglycerol, CDP choline, choline, choline phosphate, lamellar bodies, omega-3 fatty acids, polyenic acid, polyenoic acid, lecithin, palmitic acid, non-ionic ethylene and/or propylene oxide block copolymers, polyoxypropylene, polyoxyethylene, poly (vinyl amine) with dextran and/or alkanoyl side chains, polyoxy ethylene ethers, phenoxy polyethoxy

alcohols, phosphatidyl choline esters, phosphatidyl ethers, tyloxapol, surfactant-associated proteins or $C_{22}H_{19}C_{10}$.

249. The method of claim 173, wherein the oligo consists of up to about 15% A.

250. The method of claim 173, wherein the oligo(s) is(are) effective to alleviate hyper-responsiveness to, and/or reduce levels of adenosine or adenosine receptor(s), and/or to alleviate bronchoconstriction, and/or asthma and /or lung allergy(ies) and/or lung inflammation, the oligo containing up to and including about 15% adenosine (A), and being anti-sense to the initiation codon, the coding region or the 5' or 3' intron-exon junctions of a gene encoding a protein associated with hyper-responsiveness to, and/or increased levels of, adenosine and/or adenosine receptor(s), and/or bronchoconsriction, and/or asthma and/or lung allergy(ies), and/or lung inflammation, or being anti-sense to the corresponding mRNA.

251. The kit of claim 165, wherein the oligo(s) are effective to alleviate hyper-responsiveness to, and/or increased levels of, adenosine, and/or to alleviate bronchoconstriction, asthma and/or lung allergy(ies) and/or lung inflammation, and/or to reduce levels of adenosine receptor(s), the oligo being anti-sense to the initiation codon, the coding region or the 5' or 3' intron-exon junction of a gene(s) encoding a protein associated with hyper-responsiveness to, and/or increased levels of, adenosine, and/or levels of adenosine receptor(s), and/or with bronchoconstriction, and/or asthma, and/or lung allergy(ies) and/or lung inflammation, or being anti-sense to the corresponding mRNA(s); the nucleic acid comprising one or more oligo(s).

252. The kit of claim 164, wherein the oligo(s) are effective to alleviate hyper-responsiveness to, and/or increased levels of, adenosine and/or adenosine receptors, and/or to alleviate bronchoconstriction, asthma and/or lung allergy(ies) and/or lung inflammation, and/or to reduce levels of adenosine receptor(s), the oligo being anti-sense to the initiation codon, the coding region or the 5' or 3' intron-exon junction of a gene(s) encoding a protein associated with hyper-responsiveness to, and/or increased levels of, adenosine, and/or levels of adenosine receptor(s), and/or with bronchoconstriction, and/or asthma, and/or lung allergy(ies) and/or lung inflammation, or being anti-sense to the corresponding mRNA(s); the nucleic acid comprising one or more oligo(s); the kit being suitable for the diagnosis or treatment of a disease or condition associated with hypersensitivity to, and/or increased levels of, adenosine and/or adenosine receptor(s), and/or bronchoconstriction and/or lung allergy(ies) and/or lung inflammation and/or asthma.

253. The method of claim 173, further comprising administering a surfactant.

254. The method of claim 253, wherein the surfactant is administered in a prophylactic or therapeutic amount. --.

s:\legal\00672\claims 02-6 (full set clean)

of the specification. This example mentions the pyrolysis of C_2F_4 fluorocarbon with either Na_2CrF_6 or Na_2TiF_6 catalyst to produce C_2F_6 fluorocarbon.

The examiner criticized this example for not stating that the product is unsaturated, particularly in view of the fact that it could be a cyclic compound as shown by Benning et al. Page 1, column 1, line 25. Since the example gives no information as to what may be produced from C_2F_{10} fluorocarbon with the catalyst, the examiner thought it insufficient to support a claim which embraces a conversion of C_4F_{10} fluorocarbon.

Appellants consider the examiner too hypercritical in making this rejection. Concerning the production of unsaturated compounds they note that the whole specification is directed to this single purpose and therefore the C_2F_6 compound produced in Example 8 must necessarily be unsaturated not cyclic. The obvious closeness of C_2F_5 and C_2F_4 as starting materials is regarded by appellants as a sufficient suggestion of the applicability of the process of Example 8 to C_2F_{10} as well as the C_2F_6 as specifically designated by the example, especially since C_2F_{10} has been specifically disclosed as a starting material at several points in the specification. The inclusion of C_2F_{10} in claim 16 is therefore said to be highly reasonable.

In our opinion, the extension of Example 8 to a C_2F_{10} hydrocarbon is speculative and does not constitute proper support for a claim. The rejection of claim 16 will therefore be sustained.

[2] Appellants have retreated from the position of asserting patentability of broader claims which include saturated aliphatic polycarbon fluorocarbon compounds broadly. Under these circumstances, there is no basis for extending a specific example to embrace other compounds of this broad class than the one specifically named.

The appeal is dismissed as to claims 4 to 7 and 11 to 14.

The decision of the examiner is affirmed as to claims 9 and 16.

Patent Office Board of Appeals

Ex parte JACKSON

Opinion dated June 27, 1956

PATENTS

1. Specification—Sufficiency of disclosure (§ 62.7)

Ranges of percentages of elements in claim are not arbitrary where they are based on all examples disclosed in application in which all elements recited in claim are present.

Particular patents—Alloy

Jackson, Magnesium-Lithium Base Alloy, claim 2 of application allowed.

Appeal from Division 3.

Application for patent, Serial No. 43,057. From decision rejecting claim 2, applicant appeals. Reversed.

ADAMS, FORWARD & MCLEAN, New York, N.Y., for applicant.

Before WOLFFE, DUNCOMBE, and ASP, Examiners in Chief.

WOLFFE, Examiner in Chief.

This is an appeal from the final rejection of claim 2, the only claim remaining in the case. It reads as follows:

> 2. A magnesium-lithium base alloy, containing less than 0.1% of sodium, consisting of at least 68% of magnesium; from 1% to 13.5% of lithium; from 1% to 5% of silver; from 4% to 20% of cadmium; from 0.15% to 0.25% of zinc; from 0.05% to 0.2% of nickel; from 0.16% to 0.24% of copper; from 0.1% to 0.2% of barium; from 0.05% to 0.10% of calcium; and from 0.15% to 2% of aluminum.

No references have been relied upon.

The claim relates to magnesium-lithium alloys which contain at least about 68% of magnesium, from 1 to 13.5% of lithium and less than .1% of sodium. The composition of the claimed alloys is based on the following two discoveries: (1) that one or more of the alloying metals aluminum, cadmium, silver and zinc, when included in the above described magnesium-lithium base alloys, in amounts not appreciably greater than their solubility limits at ordinary temperatures, render the binary magnesium-lithium matrix work-hardenable and more creep resistant at room temperature; and (2) that the addition of small amounts of one or more "minor addition elements" including copper, calcium, nickel and barium, as well as many others, to the magnesium-lithium base alloy containing one or more of the

alloying metals aluminum, cadmium, silver and zinc provides an alloy of improved stability when age-hardened.

Quite a number of examples are given on page 2A of the specification to illustrate the invention. The claim under consideration is directed to the magnesium-lithium base alloys disclosed on this page of the specification in which a combination of the alloying metals aluminum, silver, cadmium and zinc is present and in which each of the minor addition elements nickel, copper, barium and calcium is also present.

Claim 2 stands rejected on the sole ground that it is based on new matter. In this connection the examiner stated in the final rejection:

> "More specifically it is held to be improper to arbitrarily set limits or ranges for the constituents of a composition when there is no proper coordination for such limits or ranges in the disclosure. Take for instance the range of '1% to 6% of silver' as now recited by the claim, the justification for this range should be found at page 2-A, wherein a number of examples are presented which include silver in succeeding whole numbers from 0 to 6. * * * In the case of the cadmium content there is even less justification for the range of 'from 4% to 20%.' Isolated instances utilizing '4%,' '15%' and '20%' cadmium are not sufficient for arbitrarily assuming that all values between 4 and 20 would function in the composition in the manner applicant desires. In all probability they would and the assumption of a straight-line curve could be reasonably assumed. However in the event the curve were to dip at about 8% to 10% cadmium representing results diametrically opposed to applicant's but such values nevertheless would be covered, improperly so, by the present casting of the claim."

In his answer the examiner further stated:

> "The claim includes additionally zinc, nickel, copper, barium, calcium and aluminum all of which now are represented by ranges in this claim, none of which are to be found to be disclosed as such in the specification. Page 2a of the specification is a table representing 15 specific alloys but nowhere are the ranges now claimed disclosed as such. Moreover, the reason for the ranges selected is not apparent from a study of page 2a. The values for silver and cadmium were mentioned in the final rejection letter as tending to indicate merely an arbitrary selection. There does not appear to be a satisfactory explanation in the brief that the ranges selected are not in fact arbitrary."

In support of the position taken by him the examiner cited Ex parte Kingston, patent file No. 2,894,919, and In re Davidson, 1941 C.D. 121, 47 USPQ 440.

[1] We have considered the position taken by the examiner with care but we are constrained to hold that it is not sufficiently well founded. As indicated above the ranges recited in the present claim are based on all of the examples disclosed in the present application in which all the elements recited in the claim are present. These ranges, in contradistinction to the ranges recited in the claims ruled on in Ex parte Kingston, supra, are, therefore, not arbitrary. The situation in the present case is, in our opinion, similar to that in Ex parte Kurtz, patent file No. 2,600,985, where we held:

> "It appears to us that since the Office places much emphasis on the disclosure of the examples which are present in the specification, it is ordinarily not improper to use all of the examples to set up a range of established operativeness. We find the decision in Ex parte Kingston, patent file No. 2,894,919, inapposite here, because in that case the new limits were not based on examples."

In re Davidson, supra, which is also relied on by the examiner to support his decision, is, in our opinion, not controlling here because in that case the claims as amended were held to be inconsistent with the original disclosure. This cannot be said about the claims presently before us.

As regards the range of cadmium recited in the claim the examiner admits that in all probability all values between 4% and 20% of cadmium "would function in the composition in the manner applicant desires," and that the assumption of a straight-line curve is reasonable. In view of this admission on the part of the examiner, it appears to us that the range of cadmium should not be objected to.

Accordingly, we will not sustain the rejection of claim 2 on the ground that it is based on new matter.

The decision of the examiner is reversed.

appellants and Office, the feature essential to producing the useful results of the disclosed novel process and novel product was considered to be calendering, as recited in the patent claims, and that such was a mistake of fact. The reason for this holding, and the reason why the particular mode of densifying, as set out in the patent claims, is considered immaterial, we stated in our consideration of the rejection of the claims as broader than the disclosure.

The record of the instant reissue requires consideration of a first reissue application, namely Serial No. 675,289, filed July 27, 1957. It was in this now abandoned reissue application (which constitutes a part of the record of the instant reissue application) that the examiner brought out the fact that the disclosure shows that limitation of water to wet the coating but to avoid wetting the paper web was essential. We agree with this viewpoint for the reasons given in reversing the "functional at the point of novelty" rejection, and appellants agree therewith, as shown by the record of the instant reissue application, including reissue oath and brief.

Therefore, the claims are narrowed in a respect essential to patentability, and broadened by omission of an immaterial limitation.

Thus, this situation is not that of decisions, such as Leggett et al. v. Avery et al., 17 O.G. 445, 1880 C.D. 283, 101 U.S. 256; Riley v. Broadway-Hale Stores, Inc., et al., 98 USPQ 433; In re Byers, 43 CCPA 802, 705 O.G. 444, 230 F.2d 451, 1956 C.D. 133, 109 USPQ 33, where the sole difference in the reissue application claims was to omit limitations added during prosecution of the original case, so as to cause the reissue claims to be in *all* respects as broad or broader than one or more original claims. The factor of the reissue claims being narrower in another respect introduces a completely different question. Such narrowing in the instant case is (as above brought out) in an essential feature, not an immaterial feature, so that In re Wadsworth et al., 27 CCPA 735, 515 O.G. 6, 107 F.2d 586, 1940 C.D. 73, 43 USPQ 480, which considered a reissue claim which differed from a cancelled original claim only by adding recitation immaterial to patentability, is not in point. In the noted types of cases there was clearly an attempt to recapture subject matter of cancelled or amended claims.

[2] The instant situation is that of Robert et al. v. Krementz, 243 F. 877. There, as here, the reissue claims were broader in some respects and narrower in others, *the limitations that narrowed causing the claims to define for the first time the patentable invention disclosed.* Thus, in that case, as here, the claims of the patent, as well as the claims cancelled or amended during prosecution of the parent application, failed to define the patentable invention disclosed. There the court, as we do here, decided that the definition for the first time of a patentable combination was not an attempt to recapture the subject matter of claims cancelled that did not define such patentable invention. They further held that the broadening of the reissue claims by omitting limitations not essential to patentability did not make the reissue improper when coupled with narrowing in a manner essential to patentability. This same viewpoint was stated in Florence-Mayo Nuway Company v. Hardy et al., 77 USPQ 439, and has been before followed by this Board in Ex parte Sonblom, 20 USPQ 27, and Ex parte Chilton, 25 USPQ 498.

For these reasons we reverse the rejection of the claims as constituting an improper basis for reissue.

The decision of the examiner is reversed.

Patent Office Board of Appeals

Ex parte BATCHELDER AND ZIMMERMAN

Patent issued Sept. 19, 1951.

Opinion dated Sept. 28, 1960.

PATENTS

1. Claims — Specification must support (§ 20.35)

Specification — Sufficiency of disclosure (§ 62.7)

Limiting a class, generically disclosed, to a subgenus thereunder, without an original teaching of said subgenus as such, is directed to new matter not supported by original specification; while scope of claimed term is not expanded with relation to disclosure, lesser scope subgenera to be claimed must be supported as such in original description.

Particular patents — Propellant

3,000,714, Batchelder and Zimmerman, Propellant Compositions, claims 12 and 13 of application refused.

Appeal from Division 46.

Application for patent of George W. Batchelder and Gilbert A. Zimmerman, Serial No. 399,596, filed Dec. 21, 1953. From decision rejecting claims 12 and 13, applicant's appeal. Affirmed.

D. GORDON ANGUS, Pasadena, Calif., and ROBERT C. BROWN, Azusa, Calif., for applicants.

Before ASP and SUBLE, Examiners in Chief, and LIMOFF, Acting Examiner in Chief.

LIMOFF, Acting Examiner in Chief.

This is an appeal from the final rejection of claims 12 and 13. All the remaining claims in the application, claims 7, 14 and 16 (improperly delineated "15" in the examiner's answer) have been allowed.

Claim 12 is illustrative and reads as follows:

12. A solid propellant composition comprising from about 45% to about 90% by weight of the total propellant composition of a solid, non-metallic, inorganic oxidizing salt, and from about 55% to about 10% by weight of an unsaturated polyester resin consisting of the condensation product of saturated polyhydric alcohol and polycarboxylic acid heteropolymerized with an unsaturated compound selected from the group consisting of lower alkenes, lower alkynes, phenyl substituted lower alkanes, lower alkyl dienes, lower alkenyl esters of lower alkanoic acids, lower alkenyl esters of lower alkanoic acids, lower alkyl esters of lower alkenoic acids, allyl diglycol carbonate, diallyl diglycollate and mixtures thereof; and a burning rate acceleration catalyst consisting of a mixture of from about 1.0% to about 50% by weight of ammonium dichromate and from about 99% to about 50% by weight of siliceous material selected from the group consisting of lower alkyl orthosilicates, inorganic silicates, mixtures of silicate clays with alkyl amines, lower alkoxy siloxanes, lower alkyl siloxanes, silica gel, lower alkyl titanates and mixtures thereof in an amount of from about 0.5% to about 5.0% by weight of the total propellant composition.

The issue in this appeal relates to the breadth of terminology of one ingredient of a composition employed as a solid propellant, as delineated in the claim copied above.

The appealed claims, 12 and 13, were finally rejected as being unduly broad and lacking support for the term "mixtures of silicate clays with alkyl amines." The term is considered by the examiner to be based upon new matter since the sole original description relating thereto (page 2, lines 31 and 32) was drawn to "amine treated clay." The examiner points out that while the criticized term is of narrower scope than the original description, it, nevertheless, is directed to new matter, citing In re Mraz, 36 App. D.C. 435, 1911 C.D. 316, 164 O.G. 978. The decisions cited by appellant are not considered controlling by the examiner.

The examiner has also based his rejection on the ground that the criticized term, drawn to a subclass, is not supported by a specific example since the examples drawn to ethyl silicate are not representative of said subclass, citing Ex parte Gunther, 25 J.P.O.S. 530-531, 66 USPQ 189, as to lack of support for a subgroup which is a member of a Markush group.

[1] After consideration of all of the appellant's arguments, we agree completely with the examiner and will sustain his rejection. Contrary to appellant's argument, limiting a class, generically disclosed, to a subgenus thereunder, without an original teaching of said subgenus as such, is directed to new matter which is not supported by the original specification. In re Mraz, supra, Arness v. Franks, 31 CCPA 737, 1943 C.D. 729, 557 O.G. 226, 138 F.2d 218, 59 USPQ 154, Ex parte Lindgren, Patent file 2,856,334, Paper No. 14, two pages (Appeal No. 304-61), Ex parte Kingston, Patent file 2,894,919, Paper No. 37, three pages, and Ex parte Mothes, 1904 C.D. 300, 118 O.G. 1148. While, as argued, the scope of the claimed term is not expanded with relation to the disclosure, nevertheless, lesser scope subgenera to be claimed must be supported as such in the original description.

Appellant has failed to respond to that portion of the examiner's rejection which is based upon the decision in Ex parte Gunther, supra. With the examiner, we hold the claims to lack proper support for the term "mixtures of silicate clays with alkyl amines" since there has been no exemplification of any specific member of the claimed subclass. The ethyl silicate of the examples will not support, and is not representative of, the criticized subclass.

Since the term "amine" includes many aromatic heterocyclic, cycloaliphatic and polyfunctional amines, the term in page 2 of the specification "amine treated clay" cannot be considered as delineating the claimed subclass of mixtures of silicate clays with alkyl amines.

We also note in page 2 the disclosure of "bentonite clay treated with aliphatic amines" as apparently different from the subclass of "amine treated clay." Since the term "aliphatic" includes unsaturated and polyfunctional amines, as well as the alkyl amines of the criticized term in the claims, this dis-

closure also cannot be relied upon to support the subclass now claimed.

The decision of the examiner is affirmed.

Patent Office Board of Appeals

Ex parte LAWRENCE

Patent issued Sept. 19, 1961
Opinion dated Sept. 28, 1960

PATENTS

1. Construction of specification and claims—Broad or narrow—In general (§ 22.101)

Terms of claims during prosecution are interpreted broadly and are not limited by the disclosure.

2. Construction of specification and claims—By specification and drawings—In general (§ 22.251)

Even though no prior art is cited against applicant's claim, terms of claim must be restricted so as to read upon operative classes composed of members having a general common quality exemplified by the specific description; terms of claim are not interpreted as being inclusive only of operative, or disclosed, subject matter.

Particular patents—Propellant

3,000,715, Lawrence, Propellant Compositions, claim 11 of application refused.

Appeal from Division 46.

Application for patent of Ralph W. Lawrence, Serial No. 428,791, filed May 10, 1954. From decision rejecting claim 11, applicant appeals. Affirmed.

D. GORDON ANGUS, Pasadena, Calif., and ROBERT C. BROWN, Azusa, Calif., for applicant.

Before ASP and SUHLE, Examiners in Chief, and LUDOFF, Acting Examiner in Chief.

LUDOFF, Acting Examiner in Chief.

This is an appeal from the final rejection of claim 11. The remaining claims in the application, claims 6 through 9, 12 and 13, are allowed.

The appealed claim reads as follows:

11. In the method of producing thrust for propulsion by burning in a rocket chamber a solid, non-metallic propellant composition which comprises a cured, intimate mixture of from about 45% to about 90% by weight of a solid, non-metallic, inorganic oxidizing salt, and from about 10% to about 55% by weight of the total propellant composition of heteropolymerized alkyd resin fuel component; the improvement which comprises burning said propellant composition in the presence of from about 0.5 to about 2.0% by weight of a ballistic modifying agent selected from the group consisting of tricalcium phosphate, calcium pyrophosphate, tribarium phosphate and mixtures thereof.

The issue herein relates to the breadth of definition of a term defining an ingredient in a composition used for rocket propulsion.

Claim 11 has been rejected as being unduly broad in the term "heteropolymerized alkyd resin" on the ground that the Van Nostrand Chemist's Dictionary, D. Van Nostrand Co. Inc., New York, (1953) page 550 defines heteropolymerization as "an addition polymerization which involves two or more distinct molecular species, one of which does not polymerize by itself. It does, however, enter into the polymer molecule as a distinct structural entity". The examiner holds this term to be too broad in that the specification does not set forth a sufficient number of examples to represent this broad class of compounds. The criticized composition is a mixture of components which must interact to perform their desired function and a difference in the interreaction of one of the components would, obviously, enormously affect its use as one of the components of a solid rocket propellant.

The examiner holds the description in page 1 of the specification, of the incorporation of certain alkaline earth metal phosphate salts into an "alkyd resin type" propellant not to suggest, or even to hint at, the incorporation of such additives into all possible "heteropolymerized alkyd resins" for the same purpose and function. The examiner does not consider the decisions cited by appellant to be controlling.

After carefully considering all of appellant's arguments, and the decisions cited in pages 2 and 3 of appellant's brief, we agree completely with the examiner's position and will sustain his rejection. It is apparent that the criticized term "heteropolymerized alkyd resin" includes alkyd resins of all types and varieties polymerized with any possible additional reagent including, not only olefinic compounds of the types exemplified in the description, but also a host of nonrelated polyfunctional agents, which will crosslink with reactive

Patent 2,964,083 is valid, enforceable, infringed, and not licensed. This holding (but not the accounting) is specifically directed to the infringement of representative Claims 1, 3-5, 7, 13, 14, 17-19, and 22 by representative Stock A, Blend 2, and Blend 5 (and tires whose treads are made therefrom) in view of the pretrial order limiting trial to those representative stocks and claims.

Court of Customs and Patent Appeals

In re WELSTEAD

No. 8622 Decided Aug. 3, 1972

PATENTS

1. Court of Customs and Patent Appeals — Issues determined — Ex parte patent cases (§28.203)

Court normally does not consider new contentions and arguments not presented below.

Particular patents—Compounds

Welstead, 3-(Omega-Substituted Alkyl)-Indoles, claim 23 of application refused.

Appeal from Board of Appeals of the Patent Office.

Application for patent of William J. Welstead, Jr., Serial No. 504,087, filed Oct. 23, 1965; Patent Office Group 120. From decision rejecting claim 23, applicant appeals. Affirmed.

G. WILLIAM KING, Richmond, Va. (A. DONALD MESSENHEIMER, Washington, D. C., of counsel) for appellant.

S. WM. COCHRAN (JACK E. ARMORE of counsel) for Commissioner of Patents.

Before RICH, Acting Chief Judge, and ALMOND, BALDWIN, and LANE, Associate Judges.

RICH, Acting Chief Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the rejection of claim 23 in appellant's application serial No. 504,087, filed October 23, 1965, for "3-(Omega-Substituted Alkyl)-Indoles." The rejection was on the ground that appellant had introduced new matter into the claim by way of amendment, in contravention of 35 U.S.C. 132. We affirm.

The Subject Matter Claimed

Appellant's application

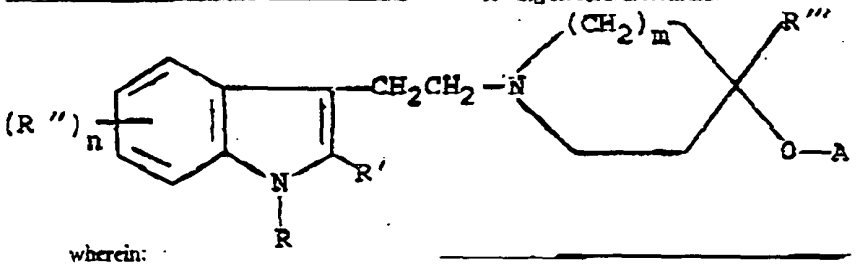
* * * relates to certain heterocyclic organic compounds which may be referred to as 3-(omega-substituted alkyl) indoles, acid addition and quaternary ammonium salts thereof, therapeutic compositions containing the same as active ingredients, and methods of making and administering them.

The compounds are said to "have utility as physiologically active agents," to be "particularly effective in diminishing the tremors and muscular rigidity of Parkinsonism," and to be "also useful as tranquilizers."

The appealed claim, with emphasis and some paragraphing supplied, is as follows:

23. A therapeutic composition for alleviating the tremors and muscular rigidity of Parkinsonism comprising

(1) administering[1] an effective amount of at least 0.1 milligram of an anti-Parkinson agent selected from the group consisting of compounds having the following structural formula:



wherein:

R is selected from the group consisting of hydrogen, lower-alkyl, lower-alkanoyl, benzoyl, phenyl, phenyllower-alkyl and cycloalkyl;

R' is selected from the group consisting of hydrogen, lower-alkyl and phenyl;

R'' is selected from the group consisting of halogen having an atomic weight less than 80, trifluoromethyl,

[1] The official copy of the application as filed does not contain this word, which seems to have crept into the certified copy of the claim on appeal through some error.

hydroxyl, lower-alkyl, lower-alkoxy and aralkoxy;

R''' is selected from the group consisting of hydrogen *when m is zero* and phenyl;

A is selected from the group consisting of hydrogen, lower-alkyl, lower-alkynyl, lower-alkanoyl, phenyl, benzoyl and N-phenyl carbamoyl;

wherein

said benzoyl, phenyl, and N-phenyl carbamoyl, contain six to nine carbon atoms and

cycloalkyl contains three to nine carbon atoms. [sic]

m is selected from zero and one and n is zero to three inclusive; [and?]

non-toxic pharmaceutically acceptable acid-addition salts thereof, and

(2) a pharmaceutical carrier.

The Rejection

The examiner rejected claim 23 "as being drawn to new matter (35 U.S.C. 132)" because of appellant's amendment inserting "when m is zero" after "hydrogen" in the recitation specifying the values of R'''. Before the amendment, R''' was defined as "selected from the group consisting of hydrogen and phenyl," and m was defined as "selected from zero and one." Accordingly, claim 23 then read on the following four possibilities:

(1) R''' = phenyl and m = 1
(2) R''' = hydrogen and m = 1
(3) R''' = phenyl and m = 0
(4) R''' = hydrogen and m = 0

In the first two cases, the indicated compounds would be piperidines; in the third and fourth, pyrrolidines. The effect of the amendment and appellant's support for the claim as amended are the two issues here.

The examiner stated that the amended form of the claim "fails to find basis in the disclosure as originally filed" and that "The grouping as now appears in claim 23, while more specific, is non[e]-the-less a new grouping."

In affirming, the Board of Appeals stated:

> The amendment had the effect of specifying 3 categories for the substituent R'''. When m is zero, R''' must be a hydrogen atom attached to a pyrrolidinyl radical at the 3-position. When m is 1, however, R''' is either hydrogen or phenyl attached to the 4-position of a piperidinyl radical. The specification did not, before the noted amendment, associate the hydrogen particularly with the piperidinyl radical at the 4-position. We find no specific disclosure, example, or illustration where there is only one substituent, i.e., only the substituent -O-A, at this 4-position.
>
> Examples 18 and 19 (page 20, last 2 compounds) do not exemplify such compounds where R''' is hydrogen.
>
> We conclude that the limitation of claim 23 had the effect of arbitrarily designating a group of materials subgeneric to the group previously claimed which was not delineated or supported as such in the original application. We note, accordingly, the pertinence of Ex parte Batchelder and Zimmerman, 131 USPQ 38 [PO Bd. App. 1960].

This is somewhat confusing. Clearly, the board interpreted appellant's amendment as excluding the *third* of the above four possibilities, and it apparently affirmed the examiner's rejection on the ground that appellant's specification as filed did not contain a written description of the genus consisting of compositions containing compounds taken only from the first, second, and fourth of the above categories, as required by the first clause of the first paragraph of 35 U.S.C. 112, and that claim 23 as amended was therefore drawn to new matter. However, the board also indicated that it found lack of support for recitation in the claim of compounds taken from the *second* of the above categories.

Appellant requested reconsideration of the board's decision. His request for reconsideration expressly approved the board's interpretation of the effect of the amendment—i.e., that when m is zero, R''' must be a hydrogen atom, but that when m is one, R''' may be either a hydrogen atom or a phenyl radical. He traversed the board's finding of lack of support for the second of the above categories, but the principal basis of his request was that

> * * * even assuming the Board to be correct [in stating that "the specification did not, before the noted amendment, associate the hydrogen particularly with the piperidinyl radical at the 4-position"], this still does not provide any basis for the rejection or for sustaining the rejection since the entire issue is whether or not applicant can claim R''' to be hydrogen when m is zero, *not when m is one and a piperidinyl radical is formed.*

Thus, at this stage of the proceeding appellant apparently viewed the issue as the existence of support for his recitation of the *fourth* category, supra.

In adhering to its original position, the board again stated that the specification as filed contained no disclosure showing R''' to be a hydrogen atom when m = 1 (second possibility, supra).

OPINION

On appeal, appellant has completely changed his position concerning the effect of the controverted amendment. Whereas he previously concurred in the board's view that it excluded from the claim those compositions containing compounds of the third type, supra, he now argues that:

> The effect of the amendment to Claim 23 was to redefine R'' to be hydrogen and [sic, or] phenyl when m = 0 and phenyl when m = 1. * * *

This excludes compounds of the second type. He also now expressly concedes that his disclosure contains no examples or recitations of invalidness with respect to compounds * * * [of the second type]. This concession, it may be noted, is in line with the board's assertion that the specification does not "associate the hydrogen particularly with the piperidinyl radical at the 4 position."

The solicitor notes this surprising shift in appellant's position and argues from it that "It would appear * * * that there is a latent ambiguity in the definition of R'' in the claim before the Court." He also argues that the court should not consider appellant's present arguments because they "are largely based on his present interpretation of the definition for R''. * * *"

[1] As the solicitor correctly contends, this court normally does not consider new contentions and arguments not presented below. Cf. In re Toiway, 58 CCPA 809, 811-12, 435 F.2d 1342, 1344, 168 USPQ 357, 359 (1971); but compare In re Land, 54 CCPA 806, 818-19, 368 F.2d 866, 874-75, 151 USPQ 621, 629 (1966). It is true that we have previously held that:

> * * * the reference to "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention" in the second paragraph of 35 U.S.C. 112 does not prohibit the applicant from changing what he "regards as his invention" (i.e., the subject matter on which he seeks patent protection) during the pendency of his application.[2]

However, we were not talking about an applicant's changing his mind between the time he argued before the board and the time he argued before the court concerning the scope of the same claim recitation.

In this case, we agree with the solicitor that we should reverse only if appellant were to persuade us that the amended claim, as *interpreted below*, defined a genus (in this case, a subgenus of the genus recited in claim 23 as filed) which was itself described in the application as filed. In addition to *In re* Batchelder, relied upon by the board, our recent opinion in Fields v. Conover, 58 CCPA 1366, 1372-74, 443 F.2d 1386, 1391-92, 170 USPQ 276, 279-80 (1971), and Judge Baldwin's concurring opinion in In re Cosler, 58 CCPA 953, 960, 437 F.2d 1397, 1404, 168 USPQ 773, 777 (1971), involving the written description requirement in other contexts, are in point. See also Bird v. Chessin, 52 CCPA 1607, 1614-15, 347 F.2d 898, 904-05, 146 USPQ 293, 297-98 (1965), and In re Shokal, 44 CCPA 854, 858-59, 242 F.2d 771, 774-75, 113 USPQ 285, 285-86 (1957). Since the specification as filed contained neither a description as such of the genus in which R'' is hydrogen or a phenyl radical when m = 1 and hydrogen when m = 0 nor descriptions of the species thereof amounting, in the aggregate, to the same thing, the rejection of claim 23 as drawn to new matter is *affirmed*.

Court of Customs and Patent Appeals

KOVAL v. BODENSCHATZ

No. 8688 Decided Aug. 3, 1972

PATENTS

1. Courts of Customs and Patent Appeals — Issues determined — Patent interferences (§28.209)

Since appellee presents no issues not raised before Board of Patent Interferences, there is no reason for court to refuse to consider appellee's arguments.

2. Interference — Reduction to practice — Tests (§41.758)

Requirements derived from objectives of one interference party that are not reflected in limitations embodied in counts ordinarily cannot be imposed on an asserted actual reduction to practice.

3. Interference — Reduction to practice — Tests (§41.758)

It is not necessary for testing to have proceeded to the point where the device is ready for commercialization in order to have an actual reduction to practice; however, there must be a relationship between test conditions and intended functional setting and tests must prove that invention will perform satisfactorily in intended functional setting.

[2] In re Saunders, 58 CCPA 1316, 1327, 444 F.2d 599, 607, 170 USPQ 213, 220 (1971).